K113584

MAR - 2 2012

510 (k) Summary

Submitter's information:

Submitter's Name:	St. Jude Medical
Address:	4 Robbins Road Westford, MA 01886 USA
Contact:	Bryan Cowell, RAC Principal Regulatory Affairs Specialist Tel: (978) 577-3473 Fax: (877)448-0353 bcowell@sjm.com
Date of preparation:	28 November 2011
Device Name:	Pressure Guidewire
Trade Name.	PressureWire®
Common/ Classification	Transducer, Pressure, Catheter Tip (870.2870) Wire, Guide Catheter (870.1330) Transmitters and Receivers, physiological signal, radiofrequency (870.2910)
Product Code	DXO, DQX and DRG
Predicate Device:	K080813 PressureWire® Aeris & Receiver.

Establishment Registration: 8030904

Establishment: St. Jude Medical Systems AB

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Device Description:

The Subject Device, PressureWire is a 0.014'' guidewire with a pressure and temperature sensor integrated into the tip to enable measurements of physiological parameters.

The PressureWire is available in 2 configurations:

- Wired version using a cable (PressureWire Certus) to connect with the diagnostic computer
- Wireless version (PressureWire Aeris).

Both PressureWire connection configurations connect to a diagnostic computer or a catheter laboratory hemodynamic recording system and are available in two lengths, 183 cm or 300 cm.

Intended Use:

PressureWire® is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a vessel. The signal output of the sensor is used for calculation and presentation of any physiological parameters, functions or indices based on temperature or pressure, e.g. Fractional Flow Reserve (FFR).

Indications for Use:

PressureWire® is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the heart and in the coronary and peripheral blood vessels.

Substantial Equivalence:

The fundamental scientific technology for the subject device is the same as for predicate device regarding signal transfer, mechanical properties and intended use. The subject device, PressureWire, meets the design inputs and raises no new safety or efficacy concerns. PressureWire is determined to be substantially equivalent to the presently marketed predicate device.

Technological Characteristics:

The modifications of design apply to the corewire and guidewire and do not change the operational principle of the device and maintains the same fundamental scientific technology as the predicate device.

Functional/ Safety testing

The verification/validation conducted indicate that PressureWire satisfy safety and performance requirements of the device specifications and do not raise additional safety issues for software or hardware.

Sterilization:

PressureWire is validated for sterilization, bioburden and endotoxin, described in report R2847-09 Sterilization Validation PressureWire.

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Biocompatibility:

Biocompatibility testing was performed in accordance with applicable standards and meets the requirements of testing standards.

Summary of performance testing

The successful completion of verification activities demonstrates that the PressureWire meets the required product specifications.

The PressureWire is substantially equivalent to the presently marketed predicate device and incorporates the required specifications with all defined requirements and risk mitigation tests having passed or mitigated. In conclusion, the PressureWire meets the design inputs and raises no new safety or efficacy concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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St. Jude Medical
c/o Bryan Cowell
Principal Regulatory Affairs Specialist
4 Robbins Road
Westford, MA 01886

Re: K113584
Trade/Device Name: PressureWire
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II
Product Code: DXO, DQX, DRG
Dated: November 30, 2011
Received: December 5, 2011

Dear Mr. Cowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113584

Device Name: PressureWire

Indications For Use: PressureWire™ is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the heart and in the coronary and peripheral blood vessels.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M A Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

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